REMARKS

Claims 28-35 are currently pending in the present application. In the Office Action mailed June 2, 2005, claims 28-35 were rejected. Applicant respectfully traverses the rejections. Claims 28-35 have been canceled, without prejudice. Applicant reserves the right to resubmit these claims, or claims of similar scope, in a continuation application. New claims 36-45 have been submitted and no new matter has been added.

Claims 29, 30, and 32-35 were rejected under 35 U.S.C. § 112, second paragraph, These claims have been canceled herein without prejudice. However, applicant asserts that new claims 36-45 do not include step plus function recitations.

Claims 32-35 were rejected under 35 U.S.C. §102(b) as being anticipated by Mueller ('528). Applicant respectfully traverses the rejection. These claims have been canceled herein without prejudice. Claims 32-35 were directed to a method of delivering medicament to tissue and included recitations of sealably engaging the distal portion of a medicament delivery catheter to a tissue surface. New claims 39-44 are directed to a method of delivering medicament to tissue while preventing medicament washout.

Claims 39-41 recite providing a medicament delivery catheter having a tissue engaging surface with at least one vacuum operated tissue stabilizer port; providing access to a tissue surface; advancing the catheter to the tissue surface; positioning the tissue engaging surface proximate the tissue surface; sealably engaging the tissue engaging surface to the tissue surface by activating a vacuum force through the tissue stabilizer port; forming a sealed opening in the tissue surface; and delivering medicament through the sealed opening in the tissue surface.

Claims 42-45 recite providing a medicament delivery catheter having a tissue engaging surface with a sealing balloon; providing access to a tissue surface; advancing the catheter to the tissue surface; positioning the tissue engaging surface

proximate the tissue surface; sealably engaging the tissue engaging surface to the tissue surface by inflating the sealing balloon; forming a sealed opening in the tissue surface; and delivering medicament through the sealed opening in the tissue surface.

Mueller ('528) discloses an apparatus and method for delivering therapeutic and diagnostic agents. The Examiner made specific reference to column 13, line 24, through column 14, line 29. In one embodiment, the accessing device 900 disclosed therein utilizes a force contact transducer 902 to permit the user to maintain device 900 against the tissue in a perpendicular manner so as to prevent seepage of the delivered drug. It is up to the user to manually maintain the accessing device 900 against the tissue surface, based upon the information provided by transducer 902, to prevent drug seepage. In another embodiment, the accessing device 1002 utilizes a corkscrew shaped tissue-penetrating implement which is withdrawn to create a seal 1006 between the accessing device 1002 and tissue 1004. However, Mueller ('528) does not teach or suggest sealably engaging the tissue engaging surface to the tissue surface by activating a vacuum force through the tissue stabilizer port or sealably engaging the tissue engaging surface to the tissue surface by inflating a sealing balloon. Thus, new claims 39-44 are patentable over Mueller ('528). Applicant also asserts that these claims are also patentable over the other references cited in the previous office action as none of the references teach or suggest sealably engaging a tissue engaging surface to a tissue surface with a vacuum force or with a sealing balloon to prevent medicament washout.

Claim 28 was rejected under 35 U.S.C. §103(a) as being unpatentable over Jenkins et al. in combination with Cox et al. and Ryan et al. Claims 29-31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Jenkins et al. in combination with Cox et al. and Ryan et al. as applied to claim 28, and further in combination with Kalloo.

To establish a prima facie case of obviousness, three basic criteria must be met by the Examiner. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the references teachings. Second, there

must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (see MPEP §2143.03). Applicant respectfully traverses the rejection.

Claims 28-31 have been canceled herein without prejudice. New claims 36-38 are directed to a method of delivering medicament to tissue while sealably traversing the atrial septum.

Claims 36-38 recite introducing a medicament delivery catheter though an endoluminal entry point and advancing the catheter through the circulatory system; directing the catheter to traverse the right atrium and puncture the atrial septum of a patient; supportively engaging the medicament delivery catheter with the atrial septum at the opening and sealing the opening; further advancing the medicament delivery catheter through the sealed opening to a surface on the chamber of the heart; and creating a channel through the surface of the heart chamber and delivering medicament into the channel.

Jenkins et al. teaches a device that can be used to create lesions in bodily orifices wherein a loop shaped probe is pushed up against tissue. Jenkins et al. also teaches a transseptal access. However, Jenkins et al. does not teach or suggest supportively engaging the catheter, sealing the septal opening and thereafter advancing the catheter through the sealed opening to create a channel in a heart chamber and deliver medicament to the channel.

Cox et al. teaches a method of epicardial ablation for creating a lesion around the pulmonary veins. The Examiner has stated that Cox et al. teaches sealing tissue around an internal chamber ablation device to prevent bleeding when the procedure is performed on a beating heart. However, Cox et al. is not directed to medicament delivery and does not teach or suggest sealing a septal opening to provide access to a heart chamber, to create a channel therein and deliver medicament thereto.

Ryan et al. discloses a transvascular TMR device and method. It discloses the creation of channels in the myocardium and the delivery of therapeutic agents. Ryan et al. specifically teaches access to the myocardium through the coronary arteries and thus teaches away from the present invention which claims traversing the atrial septum.

Kalloo is directed to methods and devices for diagnostic and therapeutic interventions in the peritoneal cavity and discloses an elongated hollow flexible tube having an interior passage sized to receive and allow a passage of an endoscope, the tube having an open distal end, first and second inflatable balloon structures defined adjacent to the distal end of the tube, and an inflation conduit extending respectively from the first and second balloon structures to receive inflation ports disposed adjacent to a proximal end of the tube for this selective independent inflation and deflation of the balloon structures. However, Kalloo does not teach or suggest traversing the atrial septum to create channels in the heart chamber and deliver medicament thereto.

The Examiner's attempt to combine the foregoing references to yield the invention of the previously presented claims required hindsight. Any attempt to combine the references to yield the newly presented claims would also require impermissible hindsight.

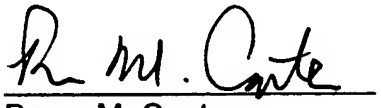
Claims 36-38 address problems and concerns that would not be evident to one who reviewed the aforementioned references. Ryan et al., which deals with the creation of channels and delivery of therapeutic agents to the myocardium, explicitly teaches access through the coronary arteries and thus teaches away from the present invention. Thus, no one would be motivated by Ryan et al. to consider a transseptal access and the concerns pursuant thereto. Jenkins et al. mentions transseptal access, but does not teach stabilization of the catheter or sealing of the septal opening. Thus, Jenkins et al, provides no suggestion of the claimed recitations. Cox et al. teaches sealing a chamber generally but does not address transseptal access either. Finally, Kalloo teaches balloon as stabilizers, but does not address transseptal access or medicament delivery to created channels.

Applicant asserts that any attempt to utilize the aforementioned references to yield the newly presented claims would by necessity require the use of these claims themselves as a roadmap. This would be tantamount to hindsight reconstruction of the claims from the references, which is impermissible.

In view of the foregoing, it is submitted that claims 36-45 are in condition for immediate allowance, and such action is respectfully requested. However, if for any reason direct communication with the Applicant's attorney would serve to advance prosecution of this case to finale, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

Respectfully submitted,

September 2, 2005



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